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(54) Title: SHROUDS FOR IMPLANTS

(57) Abstract: Shrouds (10) for use with an implant (12) in order to allow a surgeon to determine when implant (12) has been inserted into the femoral canal (or other bone as applicable) a proper distance during implantation. Such a shroud (10) is therefore useful ensuring that the patient's limb after prosthesis implantation is the correct length. Shroud (10) in a preferred embodiment contains a flange (50) which is properly positioned relative to the implant (12) in order to indicate proper insertion distance, such as by abutting a portion of the femur upon reaching correct insertion distance. The shroud (10) may contain a cap (54) which receives all or part of the neck (16) or taper (24) of the implant (12) in order to position flange (50) correctly. Alternatively, shrouds according to the present invention can attach to, connect to, or hold portions of other structure such as instrumentation for installing the implant in order to position the flange (50) relative to the implant. The shroud (10) can also help determine correct version of the implant (10), retain cement in the bone canal or cavity during implantation, pressurize the cement, and protect surfaces of the implant (12) during the implantation.

SHROUDS FOR IMPLANTS

The present invention relates to devices for locating implants properly in the bone during implant surgery.

Installation of prostheses within the patient's bone structure requires considerable effort and attention. For instance, installation of a femoral implant requires proper preparation not only of the proximal surfaces of the femur, but also proper preparation of femoral canal. Trial reduction usually follows in order to assess bone preparation and to select a properly sized and configured implant. Even with correct preparation of the bone and selection of the proper implant, the implant must be installed in proper position and orientation. In the femoral case, the implant stem must be inserted an appropriate distance into the femoral canal in order to allow the patient's leg to remain the same length as before the surgery. The femoral implant must also be located and oriented correctly in version, that is in a rotational sense relative to the longitudinal axis of the femur. Location, positioning and orientation of the femoral implant in the femur is even more difficult with cemented femoral implants. There, cement is introduced into the femoral canal and the implant then introduced into the cement, thereby allowing relative movement between the implant and the bone while the cement hardens.

Collarless implants present additional surgical challenge since they lack the landmarks which otherwise indicates to the surgeon when the implant has been inserted into the femoral canal to the proper extent, with correct positioning and orientation. Implantation of such devices can create tension and complexity during surgery, and requires considerable training, since the surgeon must gauge correct depth, positioning and orientation by eyeball without the usual reference points. Because of the gravity of the downside risk that the patient's leg will be too long or short after such surgery, implantation of collarless cemented implants has historically been reserved to a smaller group of experienced surgeons.

Previous efforts to locate, position and orient implants within the bone during implant surgery, and more particularly, femoral implants, include use of a template which may be placed on or attached to portions of the proximal surface of the femur and through which the implant stem may be inserted. The template thus positions portions of the implant it touches relative to the proximal surfaces of the femur - in both the anterior-posterior direction and the medial-lateral direction. However, such templates do not indicate when the implant has been inserted into the femur an appropriate distance.

The present invention provides devices known as shrouds which fit portions of an implant (or instrumentation attached to the implant) and indicate when the implant has been inserted a proper distance into the bone. One version of such a shroud fits the neck and shoulder of a femoral implant. The implant may, but need not be, collarless and/or adapted for installation with cement. The shroud of this preferred embodiment can feature a cap or any other structure that corresponds at least in part to the shape of the implant neck including the portions of the taper in order to hold the neck, whether loosely or tightly, or retain the shroud on the implant. (For purposes of this document, the term "hold" means to assist, however slightly and in whatever manner, releasable or not, whether by deformation of one or both structures or not, in causing two structures, such as the cap and the implant, to be in position relative to each other. Thus, the shroud can be held to the component, whether implant, instrumentation or other component, adjustably or not, using deformation properties, friction, screws, clamping, welding, integral forming, or any other technique for causing two bodies to be located adjacent to each other in whatever manner desired). A frame can connect the cap to a flange which is positioned and oriented to abut portions of the femur when the implant has been inserted a proper distance into the bone.

Accordingly, the shroud by referencing the flange to the implant (or its instrumentation) helps the surgeon determine proper insertion distance of the

implant consistent with pre-operative planning. This feature is particularly useful for collarless hip designs, but use of the invention is not limited to such designs.

The flange also helps keep cement within the femoral canal by physically impeding flow of the cement outside the canal as the implant is being inserted. The flange can also help pressurize the cement which improves surgical outcome by forcing the cement to integrate into the trabecular bone thereby improving the bond between the cement and bone interface.

The shroud can also help in evaluating the amount of version in which the stem is placed, which can affect range of motion of the prosthesis. The surgeon can use the shroud, with or without indicia, to compare position of the prosthesis to bony landmarks such as the lesser trochanter.

Shrouds according to the present invention can also help protect the neck and shoulder of the implant, including the taper. It is important not to scratch or otherwise deface the taper, which could otherwise affect the fit of the modular femoral head and the corrosion properties of the head and taper interface. Protection of the neck and shoulder also helps improve wear properties of the implant in the event they impinge on the acetabular cup which receives the femoral head.

Accordingly, the present invention includes a shroud for use with a femoral implant, the femoral implant including a stem for insertion into a canal of the patient's femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck, the shroud comprising:

A) a cap which is at least partially adapted in shape to correspond to the shape of the implants neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;

B) a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and

C) the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to a part of the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

According to the present invention there is provided a shroud for an implant that includes a stem for insertion into a cavity of a patient's bone, and an interface adapted to cooperate with other structure, the shroud comprising:

a. a locator adapted to hold the implant in order at least partially to locate the shroud on the implant;

b. a web adapted to surround at least partially the intermediate portion of the implant and to abut, at least partially, the patient's bone into which the stem is inserted, in order to assist in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance; and

c. the web and the locator connected to reference the web at a proper distance and orientation relative to the implant to allow the web to assist in determining whether the implant has been inserted into the cavity of the patients bone a proper distance.

Also according to the present invention there is provided a shroud for use with a femoral implant, the femoral implant including a stem for insertion into a canal of the patients femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck, the shroud comprising:

a. a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck

and thereby at least partially to locate and hold the shroud on the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and

c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

Further to the present invention there is provided a shroud for use with a femoral implant, the femoral implant including a stem for insertion into a canal of the patient's femur, a neck that includes a taper, and a shoulder connecting the stem and the neck, the shroud comprising:

a. a cap that includes a plurality of detents adapted to hold portions of the taper, and thereby at least partially (i) adjustably hold the shroud on the implant; (ii) locate the shroud on the implant relative to at least parts of the neck; and (iii) protect parts of the neck;

b. a flange which includes a cooperation surface and a distal surface, the cooperation surface generally accommodating portions of the implant shoulder, the distal surface adapted to (i) abut portions of the femur when the implant is properly located in the patient's femur and (ii) help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur; and

c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

The present invention also provides for a process for installing a femoral implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for the femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur, the implant including a stem for insertion into the canal of the femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck;

e. connecting to the femoral implant a shroud, the shroud comprising:

1. a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and

3. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient s femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud; and

i. placing a femoral head on the implant.

Also according to the present invention there is provided a method of performing a hip implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur, the implant including a stem for insertion into the canal of the femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck;

e. connecting to the femoral implant a shroud, the shroud comprising:

1. a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and

3. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud;

i. placing a femoral head on the implant;

j. preparing an acetabulum of the patient that corresponds to the femur with the implant;

k. installing an acetabular cup in the acetabulum;

l. placing the femoral head in proper position with respect to the acetabular cup; and

m. completing surgical operations.

In further embodiments of the present invention there is provided a femoral implant product, comprising:

1. a femoral implant which includes a stem for insertion into a canal of the patient's femur, a neck for receiving a femoral head, a shoulder connecting the stem and the neck, and a femoral head; and
2. a shroud comprising:
   a. a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;
   b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and
   c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

In certain embodiments of the present invention there is provided a femoral implant comprising:

1. a femoral implant which includes a stem for insertion into a canal of the patient's femur, a neck that includes a taper, a shoulder connecting the stem and the neck and a femoral head that connects to the neck; and
2. a shroud comprising:

a. a cap having a plurality of detents to hold portions of the taper and thereby at least partially (i) adjustably hold the shroud on the implant; (ii) locate the shroud on the implant relative to at least parts of the neck; and (iii) protect parts of the neck;

b. a flange which includes a cooperation surface and a generally flat distal surface, the cooperation surface generally accommodating and holding portions of the implant shoulder, the distal surface adapted to (i) abut portions of the femur when the implant is properly located in the patient's femur and (ii) help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur; and

c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

Further still the present invention provides a shroud for an implant that includes a stem for insertion into a cavity of a patient's bone, the shroud comprising:

a. a locator having a structure containing portions that hold structure other than the implant, the locator adapted to hold portions of said structure in order at least partially to locate the shroud relative to the implant;

b. a web adapted, when said structure holds the implant, to surround at least partially the intermediate portion of the implant and to abut, at least partially, the patient's bone into which the stem is inserted, in order to assist in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance; and

c. the web and the locator connected to reference the web at a proper distance and orientation relative to the implant to allow the web to assist

in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance.

Likewise the present invention also provides a shroud for use with a femoral implant, the shroud comprising:

a. a frame which is at least partially adapted in shape to correspond to the shape of portions of instrumentation connected to the implant, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and

c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

Embodiments of the present invention also provide for a process for installing a femoral implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for the femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur using instrumentation;

e. connecting to the instrumentation a shroud, the shroud comprising:

1. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and

3. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud; and

i. placing a femoral head on the implant.

A method of performing a hip implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for the femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur using instrumentation;

e. connecting to the instrumentation a shroud, the shroud comprising:

1. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and

3. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud;

i. placing a femoral head on the implant;

j. preparing an acetabulum of the patient that corresponds to the femur with the implant;

k. installing an acetabular cup in the acetabulum;

l. placing the femoral head in proper position with respect to the acetabular cup; and

m. completing surgical operations.

A femoral implant product, comprising:

1. a femoral implant; and

2. a shroud comprising:

a. a frame which is at least partially adapted in shape to hold portions of structure other than the implant in order at least partially to locate the shroud relative to the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur, and

c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in

the patient s femur, thereby indicating such proper location of the implant in the femur.

Further still according to the present invention there is provided a femoral implant product comprising:

1. a femoral implant adapted to be inserted into a patient using instrumentation; and
2. a shroud for use with the femoral implant, the shroud comprising:
   a. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;
   b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and
   c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

The shroud can contain any desired structure for causing it to be positionable in an adjustable fashion on the implant or on instrumentation for the implant, in order to allow the surgeon to select from a range of options as to proper insertion depth of the implant. Such adjustability can also be helpful in accommodating various sizes of implants.

The shroud can be provided in disposable or non-disposable form. It can be attached to the implant in any desired way with any desired structure, the primary objective of the invention being to provide a structure such as a

flange that is disposed adjacent to the implant with reference to at least one point on the implant (whether by attachment to the implant or to implant instrumentation) in order to assist in correctly inserting and positioning the implant during surgery.

It is therefore an object of the present invention to provide shrouds for attachment to prostheses in order to indicate proper placement of the prostheses in bone.

It is an additional object of the present invention to provide shrouds for attachment to implants in order to indicate when the implants have been inserted into the bone a proper distance.

It is an additional object of the present invention to provide shrouds for attachment to femoral implants in order to accomplish any or all of the following: to indicate when the implants have been inserted into the bone a proper distance, to indicate proper version, to retain and pressurize cement in the femoral canal, and to protect portions of the implant during surgery.

Other objects, features and advantages of the present invention will become apparent with respect to the remainder of this document.

Fig. 1 is an exploded perspective view of a first embodiment of a shroud according to the present invention for a femoral implant, combined with a femoral implant and an acetabular implant.

Fig. 2 is a perspective view of the shroud of Fig. 1 adjacent to the femoral implant.

Fig. 3 is a perspective view of the shroud of Fig. 1 positioned in place on the femoral implant.

Fig. 4 is a perspective view of the shroud of Fig. 1 on the implant which is inserted into the femoral canal.

Fig. 5 is a side elevational view of a second embodiment of a shroud according to the present invention on an implant.

Fig. 6 is a top plan view of the shroud of Fig. 5 on the implant.

Fig. 7 is a cross-sectional view of the shroud of Fig. 5, taken on line 7 - 7 of Fig. 6.

Fig. 8 is a perspective view of an alternative embodiment of a shroud according to the present invention for positioning on implant instrumentation.

Fig. 9 is a perspective view of the shroud of Fig. 8 positioned on implant instrumentation.

Fig. 10 is a side elevational view of the shroud of Fig. 9.

Fig. 11 is a perspective view of an alternative embodiment of a shroud according to the present invention for positioning on implant instrumentation.

Fig. 12 is a side elevational view of the shroud of Fig. 11.

Fig. 13 is a front elevational view of the shroud of Fig. 11.

Fig. 1 shows a preferred embodiment of a shroud (10) according to the present invention exploded from an implant (12). Implant (12) may be a femoral implant which is affixed in the femur with or without bone cement. It may include or exclude a collar at the shoulder, and it may include or exclude porous coated surfaces for bone fixation. In general, implant (12) includes a stem (14), which is generally elongated and adapted structurally for insertion

into the femoral canal, a neck (16) which includes structure (18) for receiving a femoral head (20), and a shoulder (22) that connects the stem (14) and the neck (16). The femoral head (20) may be essentially spheroid in shape and contain structure for receipt of companion structure (18) on neck (16). Usually, neck (16) structure (18) is in the form of a taper (24) which in turn includes a proximal surface (26), a relief and a frustoconical surface (30) which may act in Morse taper fashion with respect to cavity (32) in femoral head (20).

The shoulder (22) of implant (12) may but need not contain a collar (unshown) for partial abutment against portions of the femur, but the present invention is particularly well suited for implants (12) without such collars or with collars which may not provide sufficient indication of correct positioning of implant (12) in the femur or retention of cement in the femoral canal.

Femoral implant (12) may therefore be collarless or with a collar, and it may be adapted for cement fixation in the femoral canal or fixation without cement. It may but need not include porous coated surfaces for bone ingrowth. Implant (12) is typically formed of metallic material having the right corrosion resistance, strength and cost parameters. In short, implant (12) can be any desired femoral implant formed according to any desired design with any materials, for fixation in the femoral canal by whatever process or means.

Femoral head (20) may be formed of metallic material, polymeric, ceramic or other desired material. Head (20) fits in an acetabular cup which has been inserted in the acetabulum of the patient that corresponds to the femur having the femoral implant (12), The cup may include a liner such as a polymeric liner (36) to receive head (20). The liner (36) may move in gross motion generally corresponding to a portion of the motion between the torso and the femur (so-called articulation) or the liner (36) may be locked within the cup (34). Cup (34) need not contain a liner such as in instances where

the head (20) is formed of polymeric material or in metal-to-metal designs. Cup (34) may be fixed in the patient's acetabulum with or without cement.

Shrouds according to the present invention may also be used for other prostheses, including shoulder implants and acetabular cups (34) for indicating that the prosthesis is inserted a correct depth into the bone, for retaining and/or pressurizing cement during implantation of the prosthesis, for referencing version of the prosthesis, and/or for protecting portions of the implant during surgery. In the acetabular shroud, a flange may be placed circumferentially about the cup in order to indicate correct depth of insertion and orientation of the cup in the bone, to retain and pressurize cement, and/or to protect the cup or portions of it. In the shoulder implant, the shroud could be structured and act similarly to the preferred embodiment disclosed herein.

In the preferred embodiment of shroud (10) shown in Fig. 1, implant (12) is a collarless implant which is adapted for cement fixation within the femoral canal. Accordingly, the surgeon faces difficulty in determining when stem (14) has been inserted a proper distance into the cement-filled femoral canal during implantation. Furthermore, the surgeon can face difficulty in determining whether implant (12) is oriented in version with respect to the femur. Shroud (10) is adapted to help the surgeon in either of these determinations, or both of them, as well as to help retain and pressurize cement in the canal during implantation, and for other desired purposes. The structure of the shroud (10) does not matter, generally, so long as it allows shroud (10) to dispose a flange (50) adjacent to shoulder (22) of implant (12) in whatever manner to reference flange (50) in distance and/or angular orientation relative to another part of the structure of the implant (12) (whether by attachment to the implant (12) or instrumentation attached to implant (12) in order to allow flange (50) to indicate to the surgeon when the stem (14) has been inserted a proper distance into the femoral canal, or when implant (12) is located correctly in the femoral canal in version.

Flange (50) can assume any desired shape. It can be generally collar shaped as are collars on some implants. It preferably has a generally flat distal surface (53) for abutment against a portion of the femur in order to indicate to the surgeon proper stem insertion distance. The distal surface (53) need not be flat or of any other shape; instead, it can be of any desired shape to abut parts of the femur in order to allow the shroud (10) to indicate when the implant (12) has been inserted to the correct depth in the femoral canal. Flange (50) can be larger than the typical collar found on some implants, particularly if shroud (10) functions to retain bone cement in the canal during stem insertion. Flange (50) may contain a recess or cooperation surface (51) which allows it at least partially to surround shoulder (22) of implant (12) and hold, whether loosely or tightly, the shoulder (22). Flange (50) may, but need not be, oriented in angle in the same way as a collar of a collared implant. It may, for instance, but need not be, oriented generally perpendicular to the longitudinal axis (52) of neck (16) and taper (24).

One way of properly positioning and orienting flange (50) relative to implant (12) is to do so as the preferred embodiment shown in Fig. 1 does so. There, a cap (54) is structurally configured in size and shape to fit portions of neck (16) of the implant (12). Cap (54) in the preferred embodiment shown in Fig. 1 is configured to be generally cylindrically or frustoconically shaped to receive taper (24) to form a sort of cage about taper (24). Cap (54) need not fit the taper (24) or neck (16) perfectly or even closely; it can correspond to the taper (24) or neck (16) in shape, which means for purposes of this document that cap (54) can have any shape desired to be positionable on or near taper (24) or neck (16) in order to hold the neck (16), taper (24) implant (12), or any portion or portions of those structures (or any part of the instrumentation used with implant (12)), in order to reference the flange (50) relative to the implant (12).

One advantage which can be provided by the invention is a flange (50) or other structure indicating positioning that can be adjustably positioned relative to the implant, in order to give the surgeon a range of options as to how deeply or otherwise how to install the implant in correct position. One way to do this is as shown in Fig. 1, where cap (54) contains at least two, preferably more, most preferably three detents (60) which hold relief or lip (28) of the taper (24). More than one detent allows the shroud (10) to be retained on the implant (12) in an adjustable fashion, and thereby to have a degree of control of where the flange (50) is positioned relative to the implant (12). Such control thereby allows the surgeon to select the extent to which the implant (12) will be inserted or otherwise positioned in the femoral canal as indicated by the flange (50). For purposes of this document, the term "detent" means any structure which can hold the shroud relative to the implant or its instrumentation. Detent or detents (60) can be formed, among other ways, of irregularities such as indentations into the surface of cap (54), protuberances from that surface, or other irregularities, and they can be formed at points on the surface or extend in arcuate fashion around the surface to whatever extent desired.

The cap (54) can perform its holding function with or without different structure. As shown in Figs. 4 - 6, cap (54) need not contain detents (60); instead it can conform to some degree to the shape of the taper (24), with or without partial deformation of the cap (54); in such designs, the cap (54) references the flange (50) relative to the implant (12) relative to the proximal surface (26) of the taper (24). The cap (54) could just as easily hold or retain only portions of the proximal surface (26) of taper (24) and relief (28), without holding or retaining much, if any, of the frustoconical surface (30); alternatively, it could hold or retain portions of the proximal surface (26) and the thinner portions of neck (16) located distally of taper (24). In short, cap (54) may be of any desired shape and structure to hold or retain any portion of implant (12) (or instrumentation attached to it), but preferably a portion of neck (16) of implant (12)), in order to reference in position and orientation the

flange (50). Cap (54) can also surround and "cover" a greater portion of taper (24) and neck (16) and/or other portions of the implant (12) if protection of those members during implantation or at other times is desired.

The shroud can be held to the implant, or any other component such as instrumentation, using any desired technique or structure. Any portion of the shroud can hold any portion of the implant or other component. Again, for purposes of this document, the term "hold" means to assist, however slightly and in whatever manner, releasable or not, whether by deformation of one or both structures or not, in causing two structures, such as the cap and the implant, to be in position relative to each other. Thus, the shroud can be attached or held to the component, whether implant, instrumentation or other component, adjustably or not, using deformation properties, friction, screws, clamping, welding, integral forming, or any other technique for causing two bodies to be located adjacent to each other in whatever manner desired.

A frame (56) which may be configured to have any desired structure of any shape, can connect flange (50) and cap (54) in order to allow flange (50) to be stably positioned relative to cap (54) in distance and orientation. There need not be a frame (56); cap (54) can simply be connected to flange (50) directly. Flange (50) may, but need not, assist in being so properly positioned by holding, whether loosely or tightly, or retaining, part of shoulder (22) of implant (12). In the preferred embodiment shown in Fig. 1, frame (56) is a set of longitudinal members that span cap (54) and flange (50). It could just as easily be argued that part of the frame (56) is actually part of the cap (54) and part of it is part of flange (50); the only thing that matters is that cap (54) is connected in some manner, directly or indirectly, to flange (50), and any structure between portions of the two can be considered, if desired, a frame (56). If frame (56) is a recognizable structure, it can assume the configuration of a partially cylindrical member, a number of longitudinal members, a cage, or otherwise be shaped and structured as desired to position flange (50) relative to cap (54).

The shroud (10) may be formed of any desired material, such as polymeric material which can deform at least partially to be placed over portions of neck (16) of implant (12) in holding or retaining relationship. Other materials as desired may be employed to form shroud (10), and deformable to a greater or lesser extent depending upon whether shroud (10) is desired to be used with a number of different sizes of implant (12).

Fig. 2 shows shroud (10) in the process of being placed on implant (12). Fig. 3 shows the shroud (10) in place on the implant and Fig. 4 shows the shroud (12) inserted in the femoral cavity. The flange (50) is thus disposed, distanced and oriented relative to the shroud cap (54) and the implant neck (16) so as to abut part of the femur when the implant (12) is properly located in the patient's femur thereby indicating proper location of the implant (12) in the femur. Such location may include stem insertion distance, version, or and/or desired angles or parameters. Indicia (58) may but need not be included on flange (50) or other portions of the shroud (10) to show version or other desired angles or parameters; such information can be shown simply by orientation of the flange (50), or orientation of other parts of the shroud (10).

Figs. 5 - 7 show a second embodiment of a shroud (10) according to the present invention which does not use detents (60). Flange (50) is referenced relative to the proximal surface (26) of the implant (12) taper (24), and abuts parts of the prepared proximal surface of the femur when the implant (12) has been inserted the proper length.

In use, the surgeon prepares the proximal portion and canal of a femur of a patient in a conventional manner, using broaches, reamers, instruments to shape the proximal portion of the femur, and other devices and instruments as desired. She then performs trial reduction in order to select the properly configured and sized femoral implant (12), and otherwise to

gauge dimensions, angles and other parameters that matter in correct installation and implantation, and otherwise to prepare the femur for the implant. She then introduces cement into the canal of the femur and may then place the selected femoral implant (12) with shroud (10) according to the present invention into the femoral canal with cement (the shroud (10) can be placed after insertion or partial insertion of implant (1)2 if desired). The correctly positioned flange (50) may help the surgeon to do any or all of the following, among other things: (a) determine when the stem (14) of implant (12) is inserted in the femoral canal a proper distance; (b) determine correct version of implant (12); (c) retain cement in the femoral canal; (d) pressurize the cement in the canal; and (e) protect portions of the neck (16) and taper (24).

Using the shroud (10) to help properly locate the femoral implant (12) in the femur, the surgeon allows the cement at least partially to harden in order to affix or retain the femoral implant (12) in the femur. The surgeon then removes the shroud (10) and places the femoral, head (20) on the implant.

As to the acetabular components, the surgeon prepares the acetabulum of the patient that corresponds to the femur into which the femoral implant (12) has been fixed. Such preparation again typically involves broaches, instrumentation and other devices in order to prepare the acetabulum to receive a cemented or cementless cup, which can but need not include porous bone ingrowth coating, screws, pegs or other affixation devices. The surgeon installs an acetabular cup (34) with or without liner (36) and then orients the femoral head (20) in the cup (34) or liner (36). After determining that positioning of the prosthesis is satisfactory both statically and dynamically, the surgeon completes the operation.

Another embodiment of a shroud, denoted by numeral (110), is shown in Figs. 8 - 10. There, the shroud (110) attaches at least partially to structure or componentry other than the implant, such as instrumentation (111) for

placing the implant (12), rather than wholly to the implant itself. The instrumentation can be any structure that attaches or connects to the implant (12) for purposes of helping install the implant in the patient, orient the implant, remove the implant, or otherwise. One aim of Figs. 8 - 13 and this discussion is to show that shrouds according to the present invention do not have to attach to the implant itself to carry out the purposes of the invention; they can connect to anything or any structure. In any event, the shroud (110) shown in Figs. 8 - 10 comprises a flange (150) which, when the instrumentation (111) is attached to the implant (12), is disposed adjacent to the shoulder (22) of the implant similarly or identically to the way that the shroud (10) of Fig. 1 is disposed relative to its implant (12), and for at least generally the same purposes. The shroud (110) may have any desired structure to hold any desired portions of the instrumentation (111); Figs. 8 - 10 show one structure of many possibilities. Again, the term "hold" means to assist, however slightly and in whatever manner, releasable or not, whether by deformation of one or both structures or not, in causing two structures, such as the cap and the implant, to be in position relative to each other. Thus, the shroud can be attached or held to the component, whether implant, instrumentation or other component, adjustably or not, using deformation properties, friction, screws, clamping, welding, integral forming, or any other technique for causing two bodies to be located adjacent to each other in. whatever manner desired.

The structure of shroud (110) shown in these figures includes a flange (150) which forms part of a frame (152) which positions flange (150) and which also extends to a fitting (154) that holds a portion of the instrumentation (111). Fitting (154) shown in Figs. 8 - 10 holds instrumentation (111) using friction and via resistance, but other forces may be employed, and the fitting (154) may be structured to cooperate with any surface features of the instrumentation (111) to dispose flange (150) in order to carry out the invention. Fig. 9 shows the flange (150) positioned adjacent shoulder (22) of implant (12) when shroud (110) holds the instrumentation

(111) and the instrumentation (111) is connected or attached to the implant (12). Fig. 10 shows the flange (150)/ implant (12) relationship in side elevation, as the implant (12) is inserted into the femur. Shrouds (110) can contain detents or other structure for allowing them to accommodate various sizes and ranges of implants via adjustable connection to the instrumentation (111). As in the case of the other shrouds disclosed in this document, the instrumentation-holding shroud works for other implants as well, including shoulder implants and knee implants.

Figs. 11 - 13 show a third embodiment of shrouds according to the present invention, which are denoted by numeral (210). There, the shroud (210) attaches at least partially to instrumentation (211) for placing the implant (12), in one of many ways different from the shroud (110) of Figs. 8 - 10. The shroud (210) comprises a flange (250) which, when the instrumentation (211) is attached to the implant (12), is disposed adjacent to the shoulder (22) of the implant similarly or identically to the way that the shroud (10) of Fig. 1 is disposed relative to its implant (12), and for at least generally the same purposes. The shroud (210) of Figs. 11 - 13 includes a flange (250) which forms part of a frame (252) which positions flange (250) and which also extends to a fitting (254) that holds a portion of the end (256) of instrumentation (111). Fitting (254) shown in Figs. 11 - 13 holds instrumentation (211) using friction and via resistance and also cooperates with structure on the end (256), but other forces may be employed, and the fitting (254) may be structured to cooperate with any surface features of the instrumentation (211) to dispose flange (250) in order to carry out the invention. Fig. 12 shows a side elevation of the flange (250) positioned adjacent shoulder (22) of implant (12) when shroud (210) holds the instrumentation (211) and the instrumentation (211) is connected or attached to the implant (12). Fig. 13 a front elevation. Shrouds (210) can contain detents or other structure for allowing them to accommodate various sizes and ranges of implants via adjustable connection to the instrumentation (211). As in the case of the other shrouds disclosed in this document, the

instrumentation-holding shroud works for other implants as well, including shoulder implants and knee implants.

The shrouds (110) and (210) shown in Figs. 8 - 10 and 11 - 13 respectively may be attached to instrumentation and then used in same or similar ways as shroud (10) shown in Fig. 1, and for the same or similar purposes.

The chief aim of shrouds (10), (110) and (210) according to the present invention can therefore be seen to provide a structure such as a flange that is positioned in a known way relative to the implant (12) (or instrumentation attached to implant (12)), in order to allow the surgeon to determine when the implant (12) has been inserted a proper distance into the femur of the patient during the implantation. So long as that result is obtained, any structure which functions in any way to accomplish such positioning of the flange-structure is within the scope of the present invention. As was stated above, the shroud can also, but need not, accomplish other results such as indicate correct version of the implant, retain cement in the femoral canal during implantation, pressurize the cement, and/or protect portions of the implant neck or taper.

CLAIMS

1 A shroud for an implant that includes a stem for insertion into a cavity of a patient's bone and an interface adapted to cooperate with other structure, the shroud comprising:

a. a locator adapted to hold the implant in order at least partially to locate the shroud on the implant;

b. a web adapted to surround at least partially the intermediate portion of the implant and to abut, at least partially, the patient's bone into which the stem is inserted, in order to assist in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance; and

c. the web and the locator connected to reference the web at a proper distance and orientation relative to the implant to allow the web to assist in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance.

2. A shroud according to claim 1 in which the implant interface includes a tapered connector and the locator is adapted in shape to receive portions of the tapered connector in order to protect at least portions of the tapered connector.

3. A shroud according to claim 1 in which the locator is adapted to hold portions of the implant when the locator is at least partially deformed in shape.

4. A shroud according to claim 2 in which the locator is adapted to hold portions of the tapered connector.

5. A shroud according to claim 1 which is adapted to be located adjustably relative to the implant.

6. A shroud according to claim 1 in which the implant interface includes a taper with a lip, and the shroud locator includes a plurality of detents adapted to hold part of the lip in order to provide the surgeon a range of options in positioning the implant.

7. A shroud according to claim 1 in which the locator holds the implant removably.

8. A shroud according to claim 1 in which the web is adapted to hold portions of the implant when the web is at least partially deformed in shape.

9. A shroud according to claim 1 in which the implant is adapted to be retained in the patient's bone with bone cement, and the web is adapted in shape to help retain the bone cement in the cavity of the patient's bone when the implant is properly inserted into the cavity.

10. A shroud according to claim 1 in which the shroud contains indicia in order to assist in properly locating the implant in the cavity of the patient's bone.

11. A shroud according to claim 1 in which the web is referenced in distance and orientation relative to a lip of the interface.

12. A shroud according to claim 1 formed of polymeric material.

13. A shroud according to claim 1 in which the web and locator are connected with structure that includes at least one generally elongated member that connects the locator to the web.

14. A shroud according to claim 1 in which the locator and web are formed of deformable material in order to accommodate different sized implants.

15. A shroud for use with a femoral implant, the femoral implant including a stem for insertion into a canal of the patient's femur, a neck, and a shoulder connecting the stem and the neck, the shroud comprising:
    a. a cap which is at least partially adapted in shape to at least partially locate and hold the shroud on the implant,
    b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patent's femur; and
    c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

16. A shroud according to claim 15 in which the neck of the femoral implant is adapted for receiving a femoral head.

17. A shroud according to claim 15 in which the neck of the femoral implant includes a taper.

18. A shroud according to claims 15, 16 or 17 in which the cap adjustably holds the shroud on the implant.

19. A shroud according to claims 15 or 16 in which the cap is partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck.

20. A shroud according to claim 17 in which the cap that includes a plurality of detents adapted to hold portions of the taper, and thereby at least partially (I) adjustably hold the shroud on the implant; (II) locate the shroud on the implant relative to at least parts of the neck; and (III) protect parts of the neck.

21. A shroud according to claims 15, 17 and 20 in which the flange includes a cooperation surface and a distal surface, the cooperation surface generally accommodating portions of the implant shoulder the distal surface adapted to (I) abut portions of the femur when the implant is properly located in the patient's femur and (II) help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur.

22. A shroud according to claims 15, 16 or 19 in which the implant neck features a taper and the cap covers at least part of a proximal surface of the taper and at least part of tapered surfaces of the taper in order to locate the shroud on the implant and to protect surfaces of the taper.

23. A shroud according to claims 15, 16 or 19 in which the flange includes a cooperation surface and a generally flat distal surface, the cooperation surface generally accommodating portions of the implant shoulder, the generally flat distal surface adapted to abut portions of the femur.

24. A shroud according to claim 23 in which the generally flat distal surface of the flange is adapted to help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur.

25. A shroud according to claims 15, 16 or 19 further comprising a frame that physically connects the cap to the flange.

26. A shroud according to claims 15, 16 or 19 in which the flange is adapted to hold portions of the implant shoulder.

27. A shroud according to claims 15, 16 or 19 in which the shroud contains indicia in order to indicate proper orientation of the implant in the patient's femur.

28. A shroud according to claim 27 in which the indicia indicate proper rotational orientation of the implant in the patient's femur.

29. A shroud according to claims 15, 16 or 19 in which the neck of the implant includes a taper with a lip, and the cap includes at least one detent adapted to hold a part of the lip.

30. A shroud according to claims 15, 16 or 19 which is adapted to be located adjustably relative to the implant.

31. A process for installing a femoral implant in a patient, comprising:
    a. preparing the proximal portion and canal of a femur of the patient;
    b. performing trial reduction in order to select the femoral implant for the femur;
    c. introducing cement into the canal of the femur;
    d. introducing the femoral implant into the canal of the femur, the implant including a stem for insertion into the canal of the femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck;
    e. connecting to the femoral implant a shroud, the shroud comprising:
        1 a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur; and

3. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud; and

i. placing a femoral head on the implant.

32. A method of performing a hip implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for the femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur, the implant including a stem for insertion into the canal of the femur, a neck for receiving a femoral head, and a shoulder connecting the stem and the neck;

e. connecting to the femoral implant a shroud, the shroud comprising:

1. a cap which is at least partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of the implant neck and thereby at least partially to locate and hold the shroud on the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patients femur; and
3. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patients femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud;

i. placing a femoral head on the implant;

j. preparing an acetabulum of the patient that corresponds to the femur with the implant;

k. installing an acetabular cup in the acetabulum;

l. placing the femoral head in proper position with respect to the acetabular cup; and

m. completing surgical operations.

33. A femoral implant product, comprising:

1. a femoral implant which includes a stem for insertion into a canal of the patient's femur, a neck, a shoulder connecting the stem and the neck, and a femoral head; and
2. a shroud comprising:
   a. a cap which is at least partially adapted in shape to at least partially to locate and hold the shroud on the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the implant is properly located in the patient's femur; and

c. the cap and the flange connected in a manner that allows the flange to be distanced and oriented relative to the implant neck so as to abut part of the patient's femur when the shroud is placed on the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

34. A femoral implant product according to claim 32 in which the neck of femoral implant is adapted for receiving a femoral head.

35. A femoral implant product according to claim 32 in which the neck of femoral implant includes a taper.

36. A femoral implant product according to claims 33, 34 or 35 in which the cap adjustably holds the shroud on the implant.

37. A femoral implant product according to claims 33 or 34 in which the cap is partially adapted in shape to correspond to the shape of the implant neck in order to hold portions of neck.

38. A femoral implant product according to claim 35 in which the cap includes a plurality of detents adapted to hold portions of the taper, and thereby at least partially (I) adjustably hold the shroud on the implant; (II) locate the shroud on the implant relative to at least parts of the neck; and (III) protect parts of the neck.

39. A femoral implant product according to claims 33, 35 or 38 in which the flange includes a cooperation surface and a distal surface, the cooperation surface generally accommodating portions of the implant

shoulder, the distal surface adapted to (I) abut portions of the femur when the implant is properly located in the patient's femur and (II) help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur.

40. A product according to claims 33, 34 or 37 in which the implant neck features a taper and the cap covers at least part of a proximal surface of the taper and at least part of tapered surfaces of the taper in order to locate the shroud on the implant and to protect surfaces of the taper.

41. A product according to claims 33, 34 or 37 in which the implant neck includes a taper having a lip and the cap includes at least one detent for holding at least part of the lip.

42. A product according to claims 33, 34 or 37 in which the implant neck includes a taper and the cap includes a plurality of detents for holding at least part of the taper in order to provide the surgeon a range of options in positioning the implant.

43. A product according to claims 33, 34 or 37 in which the flange is generally annular in shape and features a generally flat distal surface, the annular shape generally accommodating portions of the implant shoulder, the generally flat distal surface adapted to abut portions of the femur.

44. A product according to claim 43 in which the generally flat distal surface of the shroud flange is adapted to help retain bone cement in the canal of the patient's femur when the implant is inserted into the femur.

45. A product according to claims 33, 34 or 37 further comprising a frame that physically connects the cap to the flange.

46. A product according to claims 33, 34 or 37 in which the flange is adapted to hold portions of the implant shoulder.

47. A product according to claims 33, 34 or 37 in which the flange contains indicia in order to indicate proper orientation of the implant in the patient's femur.

48. A product according to claim 47 in which the flange indicia indicate proper rotational orientation of the implant in the patient's femur.

49 A shroud for an implant that includes a stem for insertion into a cavity of a patient's bone, the shroud comprising:

a. a locator having a structure containing portions that hold structure other than the implant, the locator adapted to hold portions of said structure in order at least partially to locate the shroud relative to the implant;

b. a web adapted, when said structure holds the implant, to surround at least partially the intermediate portion of the implant and to abut, at least partially, the patient's bone into which the stem is inserted, in order to assist in determining whether the implant has been inserted into the cavity of the patient's bone a proper distance; and

c. the web and the locator connected to reference the web at a proper distance and orientation relative to the implant to allow the web to assist in determining whether the implant has been inserted into the cavity of the patients bone a proper distance.

50. A shroud according to claim 49 in which the locator holds said structure removably.

51. A shroud according to claim 49 in which the locator holds said structure adjustably.

52. A shroud according to claim 49 in which the web is adapted to hold portions of said structure when the web is at least partially deformed in shape.

53. A shroud according to claim 49 in which the implant is adapted to be retained in the patient's bone with bone cement, and the flange is adapted in shape to help retain the bone cement in the cavity of the patient's bone when the implant is properly inserted into the cavity.

54. A shroud according to claim 49 in which the shroud contains indicia in order to assist in properly locating the implant in the cavity of the patient's bone.

55. A shroud for use with.a femoral implant, the shroud comprising:

a. a frame which is at least partially adapted in shape to correspond to the shape of portions of instrumentation connected to the implant, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient s femur; and

c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

56. A shroud according to claim 55 in which the frame holds the instrumentation removably.

57. A shroud according to claim 55 in which the frame holds the instrumentation adjustably.

58 A shroud according to claim 55 in which the frame is adapted to hold portions of the instrumentation when the frame is at least partially deformed in shape.

59. A shroud according to claim 55 in which the implant is adapted to be retained in the patient's femur with bone cement, and the flange is adapted in shape to help retain the bone cement in the cavity of the patient's femur when the implant is properly inserted into the cavity.

60. A shroud according to claim 55 in which the shroud contains indicia in order to assist in properly locating the implant in the cavity of the patients femur.

61. A process for installing a femoral implant in a patient, comprising:
    a. preparing the proximal portion and canal of a femur of the patient;
    b. performing trial reduction in order to select the femoral implant for the femur;
    c. introducing cement into the canal of the femur;
    d. introducing the femoral implant into the canal of the femur using instrumentation;
    e. connecting to the instrumentation a shroud, the shroud comprising:
        1. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and

3. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud; and

i. placing a femoral head on the implant.

62. A method of performing a hip implant in a patient, comprising:

a. preparing the proximal portion and canal of a femur of the patient;

b. performing trial reduction in order to select the femoral implant for the femur;

c. introducing cement into the canal of the femur;

d. introducing the femoral implant into the canal of the femur using instrumentation;

e. connecting to the instrumentation a shroud, the shroud comprising:

1. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;

2. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is

placed relative to the implant and the implant is properly located in the patient's femur; and

3. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient' s femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur;

f. properly locating the femoral implant in the femur using the shroud;

g. allowing the cement at least partially to harden in order at least partially to retain the femoral implant in the femur;

h. removing the shroud;

i. placing a femoral head on the implant;

j. preparing an acetabulum of the patient that corresponds to the femur with the implant;

k. installing an acetabular cup in the acetabulum;

l. placing the femoral head in proper position with respect to the acetabular cup; and

m. completing surgical operations.

63. A femoral implant product comprising:

1. a femoral implant; and

2. a shroud comprising:

a. a frame which is at least partially adapted in shape to hold portions of structure other than the implant in order at least partially to locate the shroud relative to the implant;

b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patent's femur; and

c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

64. A femoral implant product comprising:

1. a femoral implant adapted to be inserted into a patient using instrumentation; and
2. a shroud for use with the femoral implant, the shroud comprising:
   a. a frame which is at least partially adapted in shape to correspond to the shape of portions of the instrumentation, in order to hold portions of the instrumentation and thereby at least partially to locate the shroud relative to the implant;
   b. a flange having at least one surface which is adapted in shape to abut part of the patient's femur when the shroud is placed relative to the implant and the implant is properly located in the patient's femur; and
   c. the frame and the flange connected in a manner that allows the flange to be distanced and oriented relative to portions of the implant so as to abut part of the patient's femur when the shroud is placed on the instrumentation and the implant is properly located in the patient's femur, thereby indicating such proper location of the implant in the femur.

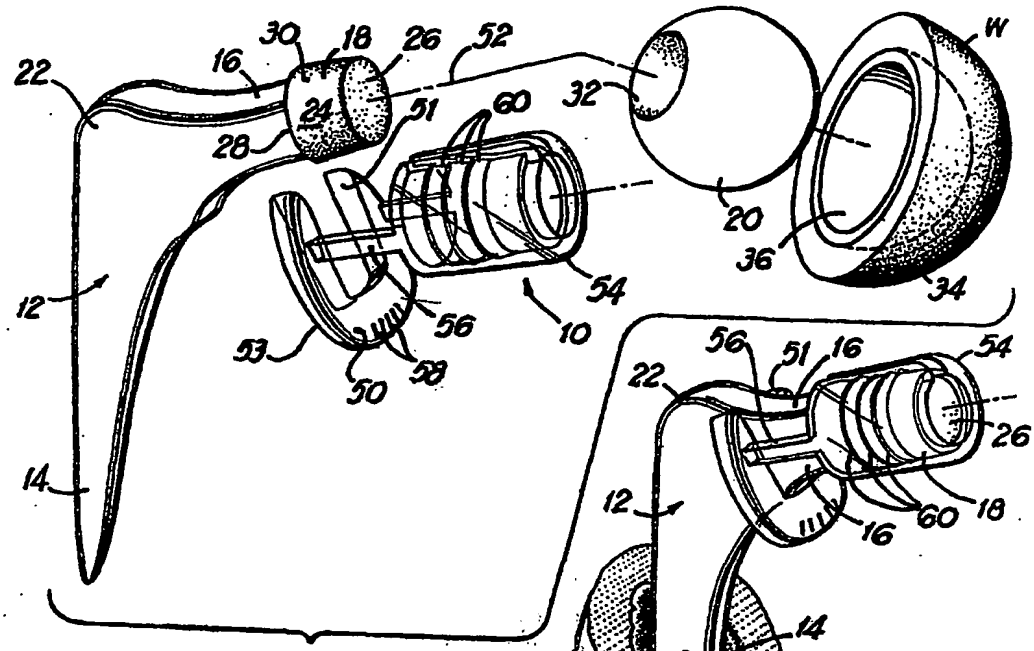


FIG 1

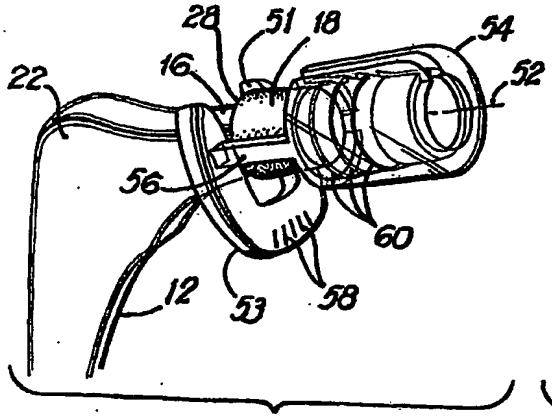
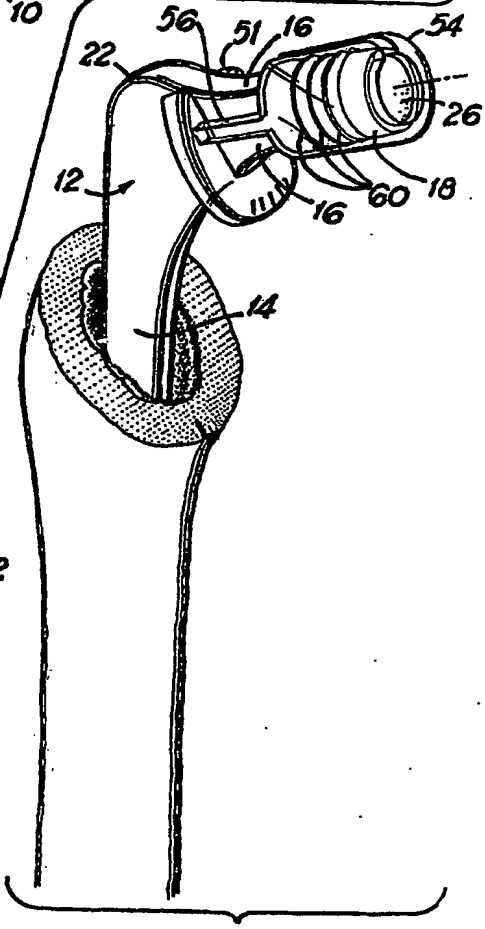


FIG 2



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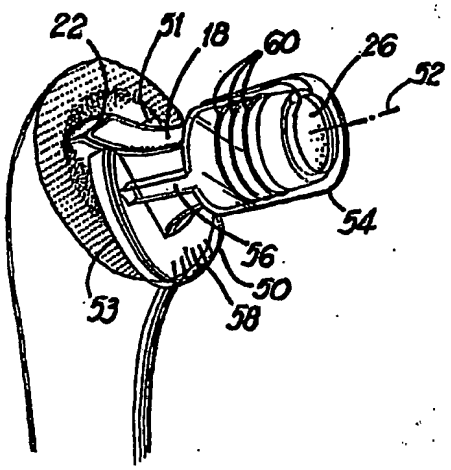


FIG 4

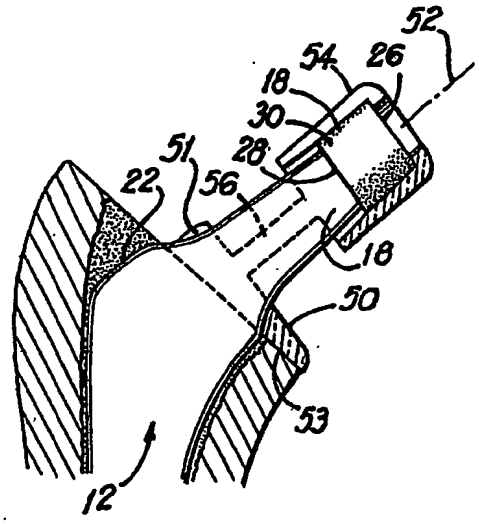


FIG 7

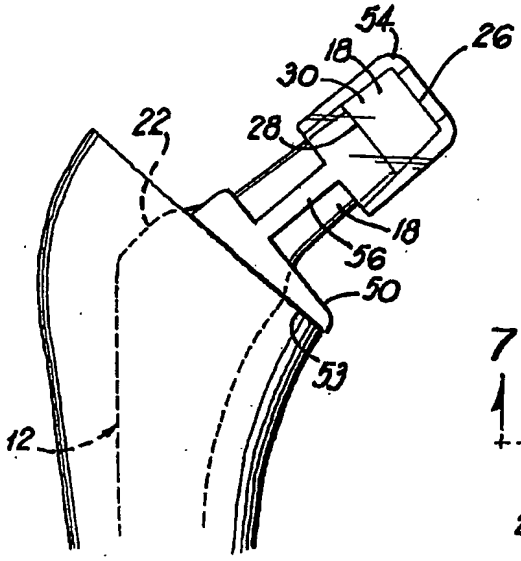


FIG 5

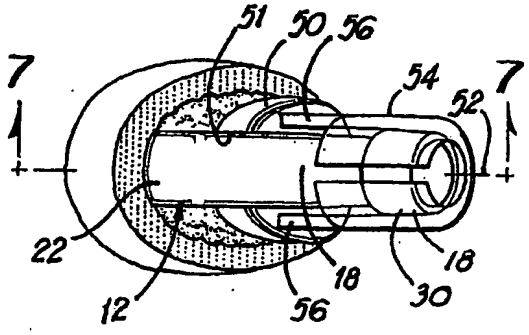
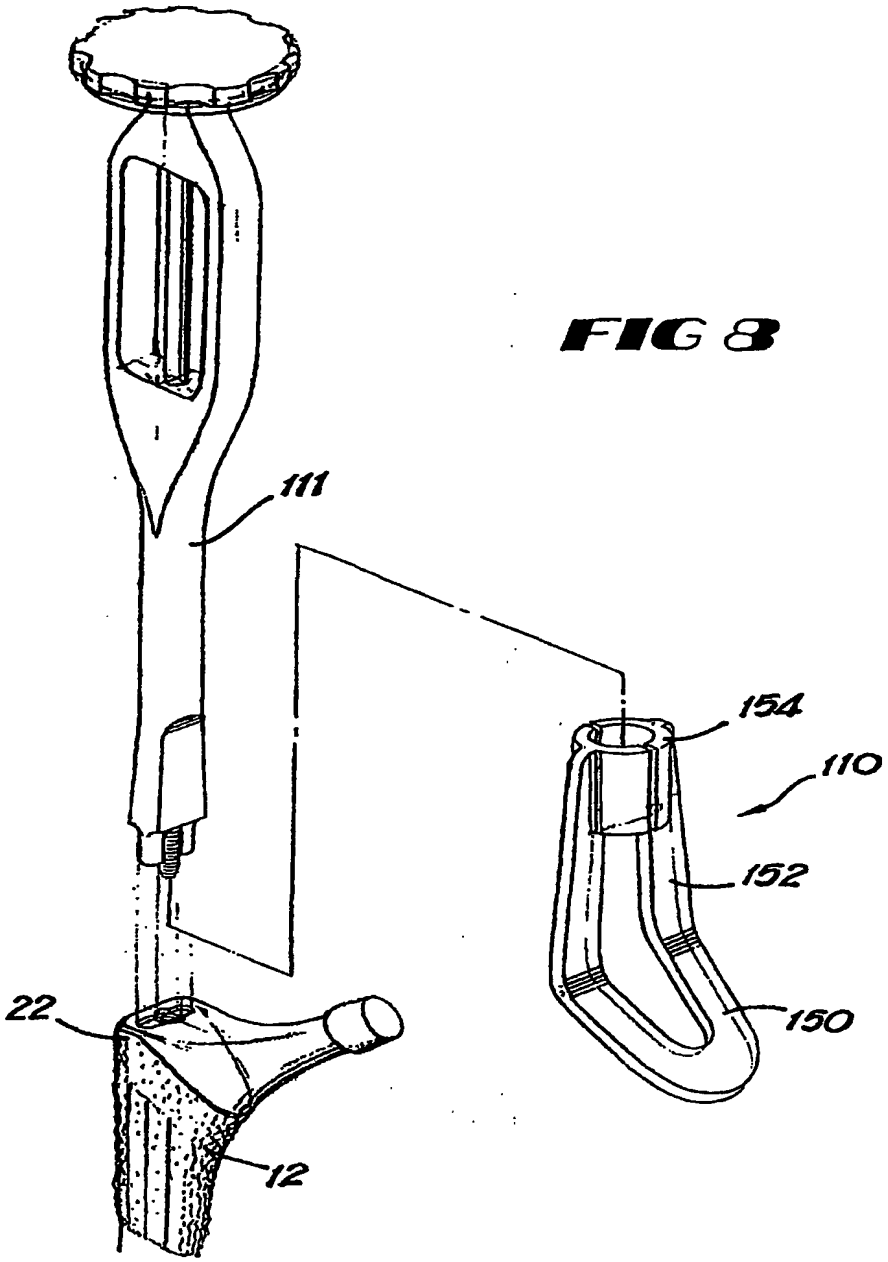


FIG 6

FIG 8



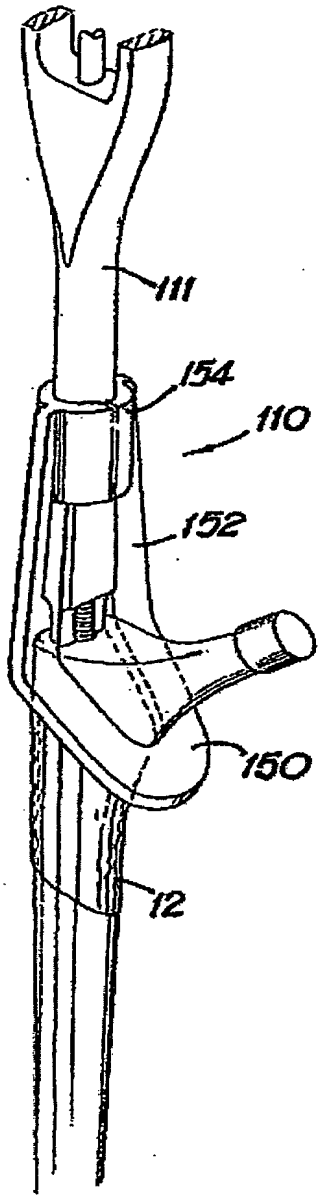


FIG 9

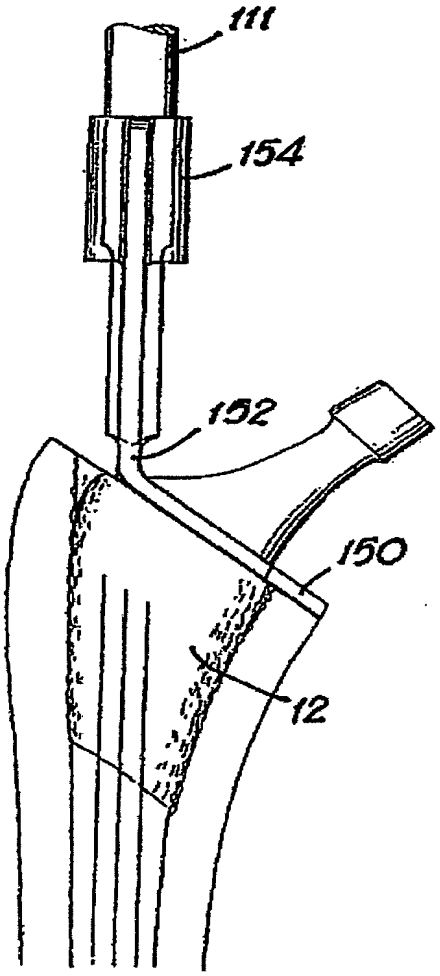


FIG 10

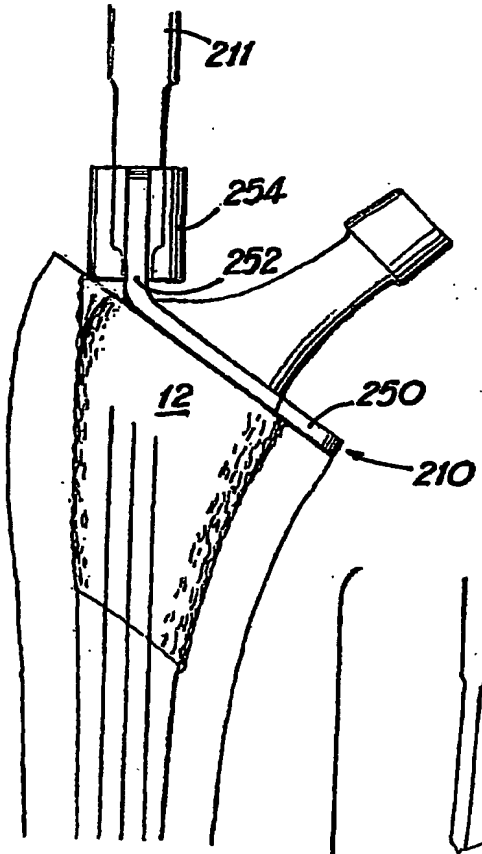


FIG 12

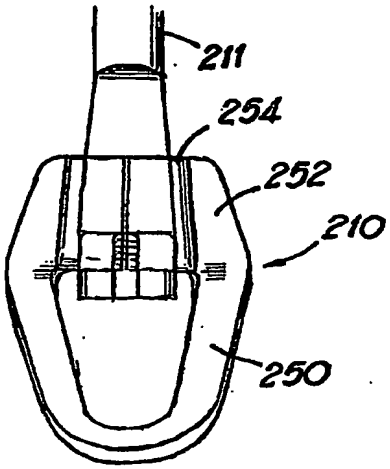


FIG 13

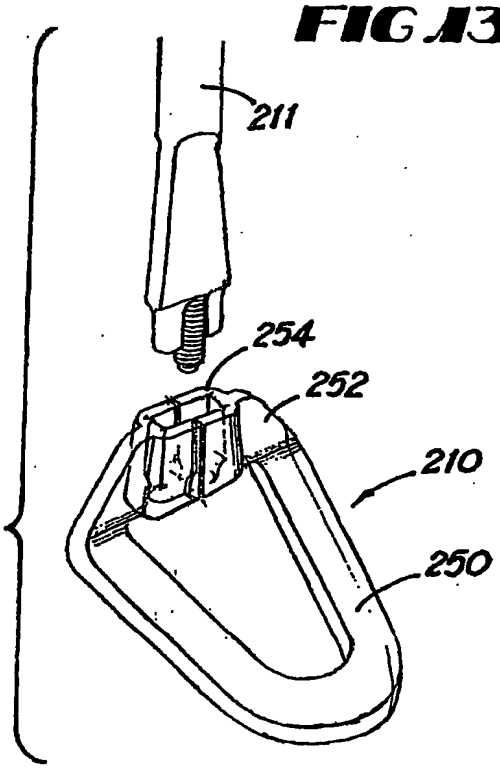


FIG 14

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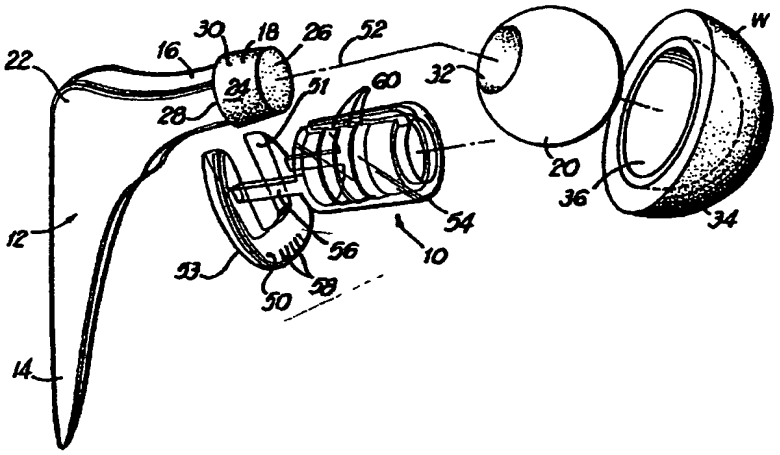
[Continued on next page]

(54) Title: SHROUDS FOR IMPLANTS



(57) Abstract: Shrouds (10) for use with an implant (12) in order to allow a surgeon to determine when implant (12) has been inserted into the femoral canal (or other bone as applicable) a proper distance during implantation. Such a shroud (10) is therefore useful ensuring that the patient's limb after prosthesis implantation is the correct length. Shroud (10) in a preferred embodiment contains a flange (50) which is properly positioned relative to the implant (12) in order to indicate proper insertion distance, such as by abutting a portion of the femur upon reaching correct insertion distance. The shroud (10) may contain a cap (54) which receives all or part of the neck (16) or taper (24) of the implant (12) in order to position flange (50) correctly. Alternatively, shrouds according to the present invention can attach to, connect to, or hold portions of other structure such as instrumentation for installing the implant in order to position the flange (50) relative to the implant. The shroud (10) can also help determine correct version of the implant (10), retain cement in the bone canal or cavity during implantation, pressurize the cement, and protect surfaces of the implant (12) during the implantation.

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INTERNATIONAL SEARCH REPORT

Int ational Application No
PCT/US 01/06052

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 940 128 A (BENOIST GIRARD & CIE) 8 September 1999 (1999-09-08) claims; figures ---	1-26,29, 30, 33-46, 49-60, 63,64
A	EP 0 940 127 A (BENOIST GIRARD & CIE) 8 September 1999 (1999-09-08) claims; figures --- -/--	1-26,29, 30, 33-46, 49-60, 63,64

[X] Further documents are listed in the continuation of box C.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 September 2001	24/09/2001

Name and mailing address of the ISA	Authorized officer
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2

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International Application No
PCT/US 01/06052

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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